

AMENDMENTS TO THE CLAIMS

Claim 1 (Currently Amended): A pharmaceutical gel preparation comprising a mixture of:

(a) D-63153 or a pharmaceutically active salt thereof in lyophilized form at a concentration of from 5 to 50 mg of peptide per ml of the preparation, and

(b) an aqueous solution of ~~an inorganic or acetic acid salt~~ sodium chloride at a concentration of from ~~0.01% to about 0.9%~~ 0.05% to about 0.5% (weight/volume), and

wherein the preparation is suitable for administration ~~either immediately~~ after reconstitution of (a) by the mixing of (a) and (b) [[or]] and after a standing time of up to about 120 minutes subsequent to the mixing of (a) and (b).

Claim 2 - 9 (Canceled):

Claim 10 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the pharmaceutical gel preparation further comprises at least one pharmaceutically active ionic peptide compound selected from the group consisting of cetorelix, teverelix, abarelix, ganirelix, azaline B, antide, detirelix, ramorelix, degarelix, or their pharmaceutically active salt and mixtures thereof.

Claim 11 (Canceled):

Claim 12 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein D-63153 is a pharmaceutically active salt.

Claim 13 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein said aqueous solution further comprises an ~~[[the]]~~ aqueous inorganic salt or acetic acid salt ~~[[is]]~~ selected from the group consisting of ~~sodium chloride~~, calcium chloride, magnesium chloride, sodium acetate, calcium acetate, magnesium acetate and mixtures thereof.

Claim 14 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the mixture is a liquid suspension or a semisolid dispersion.

Claim 15 (Canceled):

Claim 16 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of D-63153 is in the range from about 10 to about 50 mg per ml of the total amount of the pharmaceutical preparation.

Claim 17 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of D-63153 is in the range from about 20 to about 30 mg per ml of the total amount of the pharmaceutical preparation.

Claim 18 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of D-63153 is in the region of about 25 mg per ml of the total amount of the pharmaceutical preparation.

Claim 19 -28 (Canceled):

Claim 29 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the ~~inorganic salt is~~ concentration of sodium chloride, ~~and in that the concentration is in the range from 0.05% to about 0.5%~~ ranges from 0.1% to 0.2% (weight/volume).

Claim 30 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the ~~inorganic salt is~~ concentration of sodium chloride, ~~and in that the concentration is about 0.1%~~ (weight/volume).

Claim 31 (Canceled):

Claim 32 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of D-63153 is about 25 mg per ml of the preparation, and the ~~inorganic salt is~~ concentration of sodium chloride, ~~and the concentration thereof is about~~ 0.1% (weight/volume).

Claim 33 (Currently Amended): A method for producing a pharmaceutical gel preparation as claimed in claim 1 comprising ~~the steps~~

A) bringing together said D-63153 in lyophilized form and ~~an~~ said aqueous solution of ~~an inorganic or acetic acid salt~~ and

B) mixing the components.

Claim 34 (Canceled):

Claim 35 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, wherein the concentration of D-63153 is about 25 mg/ml,

and ~~the inorganic salt is~~ the concentration of sodium chloride, ~~and the concentration thereof is~~
about 0.1% (weight/volume).

Claim 36 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, further comprising ~~the step of sterilization of~~ sterilizing the peptide formulation by irradiation with gamma rays or electron beams ~~takes place~~.

Claim 37 (Previously Presented): The method for producing a pharmaceutical preparation as claimed in claim 33, where the production of (a) takes place with use of aseptic procedures.

Claim 38 (Currently Amended): A kit for producing a pharmaceutical gel preparation as claimed in claim 1, comprising from 5 to 50 mg per ml of the finished preparation of D-63153 in lyophilized form and an aqueous solution of an inorganic or acetic acid salt at a concentration of from ~~0.01% to about 0.9%~~ 0.05% to about 0.5% (weight/volume).

Claim 39 (Canceled):

Claim 40 (Previously Presented): The kit as claimed in claim 38, wherein the D-63153 lyophilizate additionally comprises mannitol.

Claim 41 (Canceled):

Claim 42 (Previously Presented): The kit as claimed in claim 38 wherein the concentration of D-63153 is about 25 mg per finished preparation and the concentration of the aqueous sodium chloride solution is about 0.1% weight/volume.

Claim 43 (Previously Presented): A method for treating a patient with D-63153, wherein a pharmaceutical preparation as claimed in claim 1 is administered subcutaneously or intramuscularly to the patient.

Claim 44 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity.

Claim 45 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 4 weeks.

Claim 46 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 8 weeks.

Claim 47 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 12 weeks.

Claim 48 (Previously Presented): A method for treating a hormone-dependent disorder in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof.

Claim 49 (Previously Presented): A method for treating prostate cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof.

Claim 50 (Withdrawn): A method for treating breast cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof.

Claim 51 (Withdrawn): A method for treating uterine myomas in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof.

Claim 52 (Withdrawn): A method for treating endometriosis in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof.

Claim 53 (Withdrawn): A method for treating precocious puberty in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof.

Claim 54 (Withdrawn): A method for modifying the reproductive function in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof.

Claim 55 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the mixture is a molecular-dispersed or colloidal mixture which may be of liquid to semisolid consistency.

Claim 56 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein a colloidal dispersion is formed by reconstitution.

Claim 57 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein a colloidal dispersion is formed by storage or leaving to stand after reconstitution and changes its viscosity as a function of time and thus improves the reproducibility of the delayed release of active ingredient.

Claims 58 - 60 (Canceled):

SUPPORT FOR THE AMENDMENTS

Claims 2-9, 11, 15, 19-24, 28, 31, 39, and 59 were previously canceled.

Claims 25-27, 34, 41, 58, and 60 are canceled herein.

Claims 1, 13, 29, 30, 32, 33, 35, 36, and 38 have been amended.

The amendment of Claims 1, 10, 12, 14, 16-18, 32-35, 37, 38, 40-43, 48-55, and 58 is supported by the corresponding claims as previously presented and originally filed, as well as page 5, lines 17-19 of the specification.

No new matter has been added by the present amendments.